

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MARCH 5, 1990

MEMORANDUM

SUBJECT: Interpretations of the EPA Medical Waste
Regulations (Numbers 36-49)

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TO: Regional, State and Territorial Medical Waste Contacts

Attached is the fifth set of interpretations for the 40 CFR Part 259 regulations for medical waste tracking and management. These questions and answers are EPA's interpretation of issues that have been raised. If you need clarifications, or if you have other questions you would like to see addressed in future documents, please call Mary Greene at (202) 475-7736, or Estelle Bulka on (202) 382-7948.

Attachment

40 CFR Questions and Answers

This document reflects the Environmental Protection Agency's interpretations of the Federal regulations at 40 CFR Part 259 - Standards for the Tracking and Management of Medical Waste. States or localities may have requirements that are more inclusive, or that pose additional restrictions on the management of medical wastes.

36. Preventative medicine and health maintenance procedures are utilized to help prevent or detect serious disease. Screening procedures are often utilized for determining the presence of certain types of diseases or adverse health conditions, such as high cholesterol. During these procedures medical wastes may be generated. Are these wastes from health maintenance medical procedures considered regulated medical waste?

Yes, regulated medical waste is defined in 40 CFR Part 259.30 (a), as any solid waste (solid, semisolid or liquid material) generated in the diagnosis, treatment, (e.g., provision of medical service), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The terms “diagnosis, treatment, or immunization” include the provision of general medical services such as surgery, dialyses, obstetrical procedures, routine checkups, and health maintenance activities. Specifically, cholesterol screening is for the purpose of “diagnosis [and] treatment...of human beings. Therefore, waste items generated during the provision of health maintenance or screening procedures, such as cholesterol screening, would be considered medical waste. However, not all medical wastes are regulated medical waste under Part 259. Items which fall into waste classes 1-7 found in Section 259.30 (a) would be considered regulated medical waste and would be subject to regulation when generated within the covered states.

37. During the course of preparing a human body for interment or cremation employees of a funeral home may utilize a variety of medical supplies and instruments. Section 259.30 (b) (1) (v) of the medical waste regulations excludes the human corpse, remains, and anatomical body parts intended for interment or cremation from regulation as a medical waste. Are items used to prepare the body for interment such as sutures, scalpels, etc., also exempt from regulation under Part 259?

No, the exclusion found at 259.30 (b) (1) (v) only pertains to the human corpse, remains or anatomical body parts which are intended for interment or cremation. Medical items or supplies used in the preparation of the body for cremation or interment would be considered medical waste since such preparation constitutes “treatment” for purposes of Part 259. See 54 FR 12339 (March 24, 1989). Thus, these wastes would be regulated if they are generated in a covered state and are listed in any of the waste classes found at Section 259.30 (a).

38. Artificial body parts and implants may be removed or replaced during surgical procedures and autopsies. Are items such as artificial body parts, implants, and pacemakers considered regulated medical waste when removed during a medical procedure, autopsy or left over from the cremation process?

Items such as artificial body parts, pacemakers, and implants are considered medical waste, but EPA does not generally consider these items “regulated medical waste”, under Part 259 because they do not fall within a waste class under 259.30. Thus, such

items are not subject to regulation under Part 259 unless they are saturated and/or dripping with blood (Class 3).

39. Medical facilities are required to properly store regulated medical waste prior to off-site transportation. However, frequently RMW is not transported directly to a disposal facility but may first go to an intermediate handler. After RMW is shipped from the medical facility, are there any storage requirements which apply to ensure the waste does not become putrescent and the integrity of the packaging remains intact until it reaches the disposal facility?

As noted, Section 259.42 requires generators of RMW in the covered states to provide:

- Storage of RMW in a manner and location that maintains the integrity of the packaging and provides protection from water, rain and wind;
- Maintain the RMW in a nonputrescent state, using refrigeration when necessary;
- Provide a lock for outdoor storage areas containing RMW to prevent unauthorized access;
- Limit access to on-site storage areas to authorized employees;
- Store the RMW in a manner that affords protection from animals and does not provide a breeding place or food source for insects or rodents.

These storage requirements apply to transporters and transfer facilities (see Section 259.70 (d)), as well as intermediate handlers of RMW (see Section 259.81 (b) (1)). Storage of RMW at a destination as defined in Section 259.80 (a) (1) are not currently covered under the Part 259 regulations. States, however, may have existing regulations to monitor destination facilities managing regulated medical waste.

40. Generators of RMW in the covered states are required to ensure their waste is packaged appropriately before the RMW can be transported or offered for transport off-site. Packaging requirements found at Section 259.41 (a) list the criteria generators must meet for packaging RMW.

A. Packaging is required to be leak resistant, although no specific container/package standards have been set. How does a generator determine if the containers and packaging being utilized meet the leak resistant requirement?

In accordance with Section 259.41 (a), packaging or regulated medical waste must meet the following criteria:

- 1) rigid
- 2) leak-resistant

- 3) impervious to moisture
- 4) sufficient strength to prevent tearing and bursting
- 5) sealed to prevent leakage

As noted in 54 FR 12346, no specific standards for containers size or composition have been developed for packaging RMW. The Part 259 regulations contain only general performance standards for packaging. This allows the generator to use one or more typed of containers to meet the above criteria. Because packaging materials vary extensively in physical and mechanical properties, the Agency did not feel it was appropriate to set specific packaging standards during the period of the demonstration program. Therefore, the most appropriate method for determining if a container or containers meet the packaging requirements with respect to its ability to be leak resistant under specific usage conditions is to subject the container/package to those conditions. This approach provides the generator with the flexibility to meet the packaging criteria using a variety of techniques.

B. Regulated medical waste containing fluids in quantities greater than 20 cc when shipped off-site for treatment and or disposal must be packaged in containers which are break resistant and tightly lidded or stoppered to prevent spillage. Often medical facilities will generate hundreds of test tubes or other small containers per day which may or may not have a lid or stopper and which may contain \pm 20 cc of fluid. How can a generator comply with the additional Section 259.41 (b) requirement to provide packaging which is tightly lidded or stoppered in these situations?

The intent of section 259.41 (b) (2) was to ensure proper management of packages of RMW containing fluids which could potentially contaminate other waste, and pose a hazard for waste handlers if released from the container. Therefore, Section 259.41 (b) (2) requires the use of break-resistant and tightly lidded or stoppered packaging for containers holding quantities of fluids greater than 20 cc. The limit of 20 cc was established based on the State of New Jersey's regulations, as a conservative estimate of the residual volume of fluid that will remain in a container after it has been emptied.

While most larger fluid containers are usually easily lidded and stoppered, medical facilities performing tests which utilize large numbers of small "containers" (i.e., small test tubes, blood vial, etc.) may find it necessary to utilize a variety of "container types" to meet all the packaging requirements of Section 259.41 (a) and (b) (2). If the containers cannot be sealed to prevent leakage, it must be placed in a plastic bag or other leak resistant container which can be sealed to prevent leakage.

41. Prior to the Medical Waste Tracking Act, radiopharmaceutical wastes generated in the medical setting were regulated by the Nuclear Regulatory Commission. Are radiopharmaceutical wastes, generated during the provision of medical care, regulated under the Part 259 regulations also?

Yes, radiopharmaceuticals which meet the definition of “regulated medical waste” are regulated by both the NRC and EPA. The regulations at 40 CFR Part 259 are not intended to duplicate the NRC regulations, but instead collect additional information. Therefore, facilities managing radiopharmaceutical wastes, generated within a covered state, must meet the requirements of both regulations. If, however, a specific requirement under either regulation is however, a specific requirement under either regulation is more stringent, the more stringent requirement must be met.

42. A health-care facility generates a variety of wastes (i.e. municipal solid waste, regulated medical waste and hazardous waste) which must be managed differently. Occasionally, these waste streams may become mixed due to employee error or lack of training. For example, a new employee mistakenly disposes of several syringes in the regular trash receptacle. The housekeeping personnel, as usual, collect the waste for disposal at the local municipal landfill. Upon inspection by employees of the landfill, the shipment is rejected when they discover the syringes in the waste. What happens if waste streams become mixed? Can the landfill owner reject municipal solid waste because it contains regulated medical waste?

Section 259.40, requires generators of regulated medical waste, in the covered states, to segregate regulated medical waste to the extent practical from other waste streams. However, under Section 259.31 (a), mixtures of RMW and municipal solid waste which do occur must be managed as RMW. While the Part 259 regulations do not preclude regulated medical waste (treated or untreated) from disposal in a municipal solid waste landfill, it is clearly the landfill owners right to reject any shipment which may contain regulated medical waste.

Additionally, when regulated medical waste which arrives at a destination facility unaccompanied by a tracking form and the owner or operator knows such a form is required, or the tracking form is incomplete or not signed, the owner or operator is required to attempt to resolve the discrepancy with the generator. If the discrepancy is not resolved the destination facility must submit a letter, within 15 days of receiving the waste, to the EPA Regional Administrator for both the State of generation and the State in which the destination facility is located as well as to the appropriate State agency for the Covered States in which the generator is located.

43. Many items which are used to provide medical care may be termed “syringe” (i.e., hypodermic syringe, water syringe, dental syringe, and irrigation syringe), but may not resemble a hypodermic syringe. Some types of “syringes” are not designed to have a needle attached for injecting or withdrawing fluids. Are all items utilized in a medical setting which are referred to as a “syringe” considered medical waste and regulated under the Part 259 regulations?

Section 259.40 (a) describes Class 4 regulated medical waste as, “Sharps that have been used in animal or patient care or treatment or in medical research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needles), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.” The intent of this regulation is to ensure proper management and prevent physical injuries from syringes with attached needles and syringes which have had the needles removed or broken, but were designed to be used with a needle. However, there are many items used in the medical setting which may be referred to as a “syringe” but were never designed to have a needle attached and thus not properly included as “sharps” (i.e. classes 4 and 7).

For example, an irrigation syringe, which may be used to clean wax and other materials from an ear passages, would not fit the intent of the regulatory description. There may be other similar items which are not utilized to inject or withdraw fluids from humans or animals. In general, if an item does not fit into one of the other regulated medical waste classes, items termed “syringe”, which are not designed to have a needle attached, would generally not be considered a regulated medical waste upon disposal. State and local regulations in the Covered States may have additional regulations which do cover these items.

44. A company manufactures a variety of microbiological media (i.e., synthetic, selective and enriched) which contains agar and various nutrients utilized in culturing specific types of microorganisms. Prior to shipping the media to hospitals, laboratories, research facilities, etc., test organisms are applied to check the viability of the media. In the process, a number of culture dishes containing media are selected for quality control and quality assurance testing. Are the cultures and culture dishes used to check the quality of microbiological media considered regulated medical waste upon disposal?

Yes, the cultures and culture dishes generated as a result of the quality control activities would be considered a RMW. As noted in Section 259.30 (a), a solid waste generated in the diagnosis, treatment or immunization of human beings or animals, in the research pertaining

thereto, or in the production or testing of biologicals and listed in Classes 1-7 would be considered a regulated medical waste. The media used to culture organisms in the medical facility often have blood, antibiotics, and agar. These ingredients are considered biologicals as defined in Section 259.10 (b). . . .” A preparation made from living organisms and their products, including, vaccines, cultures, etc. intended for use in diagnosing, immunizing, or treating human beings or animals or in research pertaining thereto.”

45. To prevent illegal use of syringes, some states have required that used syringes and needles be managed in specific ways. For instance the needle must be broken from the syringe hub and the plunger must be separated from the barrel to prevent reuse of this item for purposes other than it which it was originally intended. Does this technique meet the requirement for “treated and destroyed” found at Section 259.30 (b) (1) (iv) and become exempt from the Part 259 regulations?

No, to become exempt from the Part 259 regulations using the treated and destroyed exclusion, a regulated medical waste would have to be both treated and destroyed as defined in Section 259.10. Treated RMW has been subjected to or managed using a method, technique, or process designed to change the biological character or composition of any regulated medical waste so as to reduce or eliminate its potential for causing disease. Destroyed RMW has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing or breaking so that it is no longer generally recognizable as medical waste. The above scenario does not provide treatment for the RMW, which would reduce or eliminate its potential for causing disease. Separation of the syringe barrel and plunger may be thought of as breaking, but this does not leave the syringe unrecognizable and therefore does not meet the definition of destroyed.

46. In 54 FR 12349 of the Standards for the Tracking and Management of Medical Waste, the preamble discusses the transport of RMW by generators of less than 50 pounds per month. This discussion states the “small individual generators may find it economical to contract as part of a group for waste management services.” However, this option is not directly discussed in the regulations.

A. What requirements do small generators need to meet to use this option for regulated medical waste management?

Section 259.50 (e) (2) (I) discusses the general requirements for generators of less than fifty pounds of regulated medical waste per month. Generators who generate and transport or offer for transport less than 50 pounds of regulated medical waste in a calendar month are subject to Part 259, Subpart E and Sections 259.50, 259.51 and 259.54 (b). Generators of less than 50 pounds of RMW per month are required to comply with all pre-transport requirements found in Subpart E. These requirements

include proper segregation, packaging, storage, labeling, marking and decontamination of reusable containers (when applicable). Generators of less than 50 pounds of RMW per month can also utilize the exemptions found in Section 259.51 (a) and (c) to manage RMW. Generators utilizing these exemptions must also comply with applicable recordkeeping requirements found in Section 259.54 (b).

A generator of less than 50 pounds of RMW per month may not fall into the specific exemption areas of Section 259.50 (e) (2) or 259.51 (a) or (c) noted above. For example, a number of physicians in a building, each with their own practice, could contract with a hauling and disposal company as a group or make similar arrangements with their building maintenance company. Each physician remains a “generator” and thus is responsible for ensuring that the requirements of Subpart E., Section 259.50 and 259.54 (b) are met. Additionally, as required in Box 15 of the Medical Waste Tracking Form, any hauling, disposal facility or building maintenance company who initiates a tracking form for the group must have written authorization from the generator or generator’s representative. This is also noted in 54 FR 12349 in regard to the exemption at Section 259.51 (a) which requires a written agreement with the facility accepting the waste to ensure proper transport of the RMW.

B. Is the option to contract for RMW management limited to separate business entities located in a single building, or may tenants who lease space in a privately owned building also use this option?

Limitations on the option to contract as a group for management services of regulated medical waste is not discussed in the Part 259 regulations. In general, generators of less than 50 pounds of RMW per month may contract as a group if the regulations noted in 46A are followed.

C. Can both large and small quantity generators located in the same building form a group? What would constitute a group and what kind of documentation is needed to meet the regulations?

Any group of generators may form a group for purposes of obtaining/consolidating RMW management services. However, there are different requirements for each generator type. Generators of 50 pounds or more of RMW must comply with the requirements of Part 259, Subpart E and F, including the use of the tracking form.

As noted in 46A, Box 15 of the Uniform Waste Tracking Form requires the signature of a representative for the generator. Individuals signing for a generator in Box ? must have written authorization from the generator or the generator’s operation in order to certify the waste has been fully and accurately described, classified, packaged, marked and labeled in accordance with all state and federal laws and regulations.

In addition, a written agreement for the provision of regulated medical waste management services from a transporter, building maintenance company, etc., does not relieve the original waste generator of the legal responsibility to comply with the applicable regulations.

D. In situations where a group is formed to consolidate the RMW management activities, who is identified as the generator in Block 1 of the tracking form and who will sign the tracking form as the generator of the waste in Block 15?

When a group is formed through written agreement, the company initiating the Medical Waste Tracking Form would be identified in Box 1. For example, a group of physicians, who generate individually less than 50 pounds of RMW per month, contract with a transporter to provide RMW management services. The transporter's representative would sign in Box 1 on the tracking form on behalf of the generator. A representative of the transporter's would also sign in Box 15 on behalf of the generators. The physicians who originally generated the RMW would continue to be legally liable for that waste even though a representative of the transporter's company is initiating and signing for the generator in accordance with the written agreement.

Generators of less than 50 pounds per month are not required to complete a tracking form, and may instead choose to maintain a shipping log in accordance with Section 259.54 (b). In this situation the transporter must complete a tracking form for all RMW received from generators who generate less than 50 pounds of RMW which is accompanied by a tracking form (see Section 259.50 (e) (2) (I)).

47. A building maintenance company has a written agreement to pick up RMW from each practice within the building in packaging that is not acceptable for off-site transport.

A. The building maintenance company combines the waste in packaging which meets all the requirements for off-site transport. Are the individual generators and building maintenance company required to keep logs? If the building maintenance company takes the waste to a central collection area within the building, is a log system required?

If a group of physicians, who generate each less than 50 pounds of RMW per month, contract with a maintenance company to provide appropriate RMW management (packaging, labeling and marketing), prior to offering that waste for off-site transport, the physician is required to maintain a shipping log (See Section 259.54 (b) (1)). As noted in 54 FR 12349, building management companies may act under a written agreement and perform remanifesting or consolidation function on behalf of the transporter. In that case, the building maintenance

company would initiate and maintain all applicable tracking forms for off-site transport and comply with Section 259.76. This includes maintaining a consolidation log.

B. Who is responsible for ensuring that appropriate packaging requirements are met (i.e., inner containers, including sharps boxes and fluid containers are labeled and marked)? Which generator's identification information should be used to mark and label liners and the outermost surface of containers?

Each generator is responsible for all pre-transport requirements found in Part 259, Subpart E, which includes appropriate segregation, packaging, storage, labeling and marking. If a generating physician himself carries out Subpart E requirements, the labeling and markings on the package of RMW would reflect that. The physicians group may contract with another party, (e.g. the building maintenance personnel) to carry out these generator requirements. In this case, the information on the labels and markings should indicate the building maintenance company as the intermediate handler. A contract with another party does not relieve each generator of responsibility for maintaining a shipment log for each package of RMW or the legal liability for that waste.

48. Section 259.51 (a) (1) states that a generator of less than 50 pounds of RMW per month is exempt from the requirement to use a transporter who has notified EPA and the use of the tracking form if: the generator keeps the required log; the waste is properly packaged, marked and labeled; and the RMW is transported in the generator's own vehicle to a health care facility, an intermediate handler or a destination facility with which the generator has a written agreement to accept RMW. What specifically constitutes a health care facility?

The Part 259 regulations do not specifically define "health care facility". The exemption found in Section 259.51 (a) (1) does require the generator of less than 50 pounds per month to transport the RMW to a health care facility, a destination facility or a disposal facility. The requirement to have a written agreement with that facility to accept the RMW implies that the health-care facility is providing medical care and is itself a generator of less than 50 pounds per month, (e.g., a physician who is generating waste at her office), to bring this waste to a central health care facility, (e.g., the hospital with which the doctor is associated), without the need for a tracking which accepts RMW from an off-site generator acts as a transfer or destination facility (e.g., if they incinerate RMW on-site). As a transfer facility the health-care facility would be required to comply with any applicable transporter requirements found in Part 259 Subpart H in addition to the applicable generator and pre-transport requirements found in Subparts E and F.

49. The regulations specify recordkeeping requirements for the health-care facilities that receive the waste if the facility treats and destroys the waste on-site through incineration or some other process. What recordkeeping requirements apply if the health-care facility is consolidating and shipping the waste off-site with its own waste? For example, a private practice dentist agrees to accept waste from other dentists in his community and store the RMW until he has collected enough waste to make it economical to ship the waste off-site utilizing an authorized transporter. In this scenario, would the dentist be acting as a transfer facility, and thus subject to the transporter requirements? If not, what requirements would apply?

As noted in Question #48, a health-care facility or intermediate handler which accepts RMW from off-site generators of less than 50 pounds of RMW per month acts as a transfer facility for that waste and must comply with all Applicable Part 259 Subpart H requirements. Additionally, the generating dentists would be required to meet the applicable requirements in Subpart E and F (e.g., Sections 259.50, 259.51 (a) and 259.54 (b)).

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